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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,786	MILLER-PODRAZA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-84* is/are pending in the application.

4a) Of the above claim(s) *68-81 and 84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82 and 83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is the national stage entry of PCT/FI03/00039, filed 20 Jan 2003; and claims benefit of foreign priority document PCT/FI02/00043, filed 18 Jan 2002; this foreign priority document is in English.

Claims 68-84 are pending in the current application. Claims 68-81 and new claim 84, drawn to non-elected inventions, are withdrawn. Claims 82 and 83 are examined on the merits herein.

Election/Restrictions

Applicant's election with traverse of Group II, claims 82 and 83, in the reply filed on 24 Oct 2008 is acknowledged. The traversal is on the ground(s) that the common inventive concept of the claims is the special technical feature of the ability of the present substances to bind to *Helicobacter pylori*. This is not found persuasive because claim 68 and 72 are drawn to a *Helicobacter pylori* binding substance comprising a terminal oligosaccharide sequence. The required property of *Helicobacter pylori* binding is a property of the substance, not necessarily a property of the terminal oligosaccharide sequence alone, therefore the isoglobotriose disclosed by Angstrom et al. is a *Helicobacter pylori* binding substance comprising a derivative of the instantly claimed terminal oligosaccharide sequence, wherein the property of *Helicobacter pylori* binding is an activity related to the ceramide structure within the disclosed substance. The instant specification provides guidance that de-N-acetylation is encompassed by the

term derivatization (page 18, lines 29-32). With regard to the *Helicobacter pylori* binding property chondroitin type oligosaccharide disclosed by Jacquinet et al., MPEP 2112.01 II states "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." Athough Jacquinet et al. is silent as to the ability of the chemical composition to bind *Helicobacter pylori*, this property is necessarily present in the disclosed chemical structure that is identical to the instantly claimed structure.

The requirement is still deemed proper and is therefore made FINAL.

Newly submitted claim 84 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: new claim 84 constitutes an invention of Group IV, drawn to a method of detecting binding to *Helicobacter pylori* comprising the steps of contacting the *Helicobacter pylori* binding substance with a sample and detecting a complex of *Helicobacter pylori* and said substance. This method of detecting binding shares the common feature of common core of the oligosaccharide sequence $[Hex1(A)_{q1}(NAc)_{r1}\alpha/\beta3]_s Gal(NAc)_{r2}\beta4Glc(A)_{q2}(NAc)_{r3}$ and is found not to serve as the special technical feature of a single general inventive concept of the inventions of Groups I-IV as a known product disclosed by Jacquinet et al. (US Patent 4,943,630, issued 24 Jul 1990, of record). Athough Jacquinet et al. is silent as to the ability of the chemical composition to bind *Helicobacter pylori*, this property is

necessarily present in the disclosed chemical structure that is identical to the instantly claimed structure.

Claims 68-81 and new claim 84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 24 Oct 2008.

Claim Objections

Claim 82 is objected to because of the following informalities: the typographical error "caused by the present of *Helicobacter pylori*" appears in claim 82 of the amended claim filed 24 Oct 2008 where the previously presented claims recited "caused by the presence of *Helicobacter pylori*".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 82 and 83 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. Claim 82 recites "the substance according to claim 68..." Claim 68 recites "... and analogs or derivatives of said oligosaccharide sequence..." (emphasis added) Claim 83 depends from claim 82 and incorporates all limitations therein.

The specification discloses chemicals, such as specific analogs such as the acetamido analogs alkylamido, arylamido and secondary amine at page 19, lines 10-15 which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 82 and 83 are directed to encompass derivatives and analogs which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives and analogs meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and because chemical derivatives and analogs are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The specification provides functional limitations as to the definition of derivatives and analogs at page 19, lines 20-30.

The recitation, "structural derivatives... so that the binding to the *Helicobacter pylori* is retained or increased", at page 19, lines 20-30 is seen to be merely functional language.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the

recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the

genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115.)

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when… the evidence indicates ordinary artisans could not predict the operability … of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

Claims 82 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claims 82 and 83 are drawn to a method of treatment or prevention of a condition due to or caused by the presence of *Helicobacter pylori*. The instant specification explicitly defines treatment to encompass treatment in order to cure a disease or a condition or to prevent the development of a disease or a condition (page 32, lines 25-30). Claim 82 further recites "the substance according to claim 68..." and claim 68 recites "A *Helicobacter pylori* binding substance ... for the prophylaxis or treatment..."

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for the treatment or prevention of a condition due to or caused by the presence of *Helicobacter pylori*, wherein a pharmaceutically effective amount of the substance according to claim 68 or 72 is administered to a subject in need of such treatment.

The state of the prior art: The ordinary definition of prevent encompasses "keep from happening or arising; make impossible". See provided definition of prevent (definition of prevent, WordNet, cited in PTO-892). Prophylaxis is synonymous with prevention. The ordinary definition of cure encompasses "a complete or permanent solution or remedy". See provided definition of cure (definition of cure, Merriam-Webster Online Dictionary, cited in PTO-892). A permanent solution or remedy would make the reccurence of condition impossible. There is no prior art disclosing making a condition due to or caused by the presence of *Helicobacter pylori* impossible.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The lack of any prior art disclosing making a condition due to or caused by the presence of *Helicobacter pylori* impossible means that one skilled in the art cannot predict the usefulness of a product or method to make a condition due to or caused by the presence of *Helicobacter pylori* impossible. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims specifically includes prevention of a condition due to or caused by the presence of *Helicobacter pylori*.

The amount of direction or guidance presented: The instant specification explicitly defines treatment to encompass treatment in order to cure a disease or a condition or to prevent the development of a disease or a condition (page 32, lines 25-30). The specification as filed does not explicitly provide a limiting the definition of the term prevention or cure.

The presence or absence of working examples: The only working examples provided are for binding activity with regard to *Helicobacter pylori* in TLC overlay assays. For example, see instant specification, page 46, example 4.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as prevention or cure of a condition due to or caused by the presence of *Helicobacter pylori*. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible treatment methods beyond those known in the art, (such as prevention or cures) one skilled in the art would undertake a novel and extensive research program to show that the administration of the substance according to claim 68 or 72 made a condition due to or caused by the presence of *Helicobacter pylori* impossible. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of compounds, conditions, patient populations and treatment conditions, it would constitute an undue and unpredictable experimental burden.

> *Genentech*, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for cure or prevention of a condition due to or caused by the presence of *Helicobacter pylori*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crandall Jr. et al. (Proceedings of the Society for Experimental Biology and Medicine, 1933, 30, p704-706, cited in PTO-892) in view of the definition of chondroitin sulfuric acid (The Merck Index, 14th edition, cited in PTO-892) and in view of Kodama et al. (European Patent Application EP 1002805 A1, published 24 May 2000, cited in PTO-892). The definition of chondroitin (CHEMnetBASE, cited in PTO-892) is provided as evidence.

Crandall Jr. et al. teaches patients with peptic ulcer treated with chondroitin (page 704, lines 14-17 of paragraph 2). Crandall Jr. et al. teaches the patient

population includes patients with ulcer at the lesser curvature (page 705, lines 3-4 of paragraph 2), or a peptic ulcer of the stomach which is synonymous with gastric ulcer. Crandall Jr. et al. teaches chondroitin is used as a model compound for chondroitin sulfuric acid (page 704, lines 8-11 of paragraph 2). Chondroitin is a polymeric compound comprising repeating groups of glucuronic acid, GlcA, and N-acetyl galactosamine, GalNAc with a β1-3 glycosidic bond between GlcA and GalNAc and a β1-4 glycosidic bond between GalNAc and GlcA (definition of chondroitin, CHEMnetBASE).

Crandall Jr. et al. does not specifically teach the species of compound comprising GlcAβ1-3GalNAcβ1-4GlcAβ1-3GalNAc (instant claim 82), or two of the repeat units taught by the definition of chondroitin. Crandall Jr. et al. does not specifically teach the gastric ulcer due to or caused by the presence of *H pylori* (instant claim 82).

The definition of chondroitin sulfuric acid teaches the molecular weight is approximately 50,000 depending on source and method of preparation (page 1, paragraph 1). A molecule with a molecular weight of approximately 50,000 comprises at least two of the repeat units taught in the definition of chondroitin sulfuric acid.

Kodama et al. teaches *H pylori* is now known to play an important role in the cause of gastric disorders such as gastric ulcers (page 2, paragraphs 2-3). Kodama et al. teaches gastric disorders caused by *H pylori* are known to be treated with polysaccharides (page 2, paragraph 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Crandall Jr. et al. in view of the definition of chondroitin sulfuric acid and in view of Kodama et al. One of ordinary skill in the art would be motivated to combine Crandall Jr. et al. in view of the definition of chondroitin sulfuric acid to use chondroitin with a molecular weight of approximately 50,000 which comprises at least two of the repeat units in the definition of chondroitin because Crandall Jr. et al. teaches chondroitin is used as a model compound for chondroitin sulfuric acid and the definition of chondroitin sulfuric acid teaches teaches the molecular weight is approximately 50,000 depending on source and method of preparation. One of ordinary skill in the art would be motivated to combine Crandall Jr. et al. in view of Kodama et al. to treat patients wherein the gastric ulcer is due to or caused by the presence of *H pylori* because Kodama et al. teaches it is now known that *H pylori* plays an important role in the cause of gastric disorders such as gastric ulcers.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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